



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C., 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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MEMORANDUM

DATE: February 28, 2014

SUBJECT: Review of Denatonium Benzoate Toxicity Studies

TO: Cathryn Britton, Team Leader  
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EFED evaluated several studies on toxicity of denatonium benzoate to aquatic and terrestrial organisms (**Table 1**). Please refer to the attached DERs for additional details.

**Table 1. Data requirement**

Study	Test Species	MRID	Study Classification	Summary
850.2100	Northern bobwhite quail ( <i>Colinus virginianus</i> )	47146905	Acceptable	LD <sub>50</sub> = 196 mg ai/kg bw (95% C.I. 145-264) NOAEL = 50 mg ai/kg bw LOAEL = 100 mg ai/kg bw Endpoints affected: mortality and clinical signs of toxicity
850.2200	Northern bobwhite quail ( <i>Colinus virginianus</i> )	47146906	Supplemental	LC <sub>50</sub> = 5080 mg ai/kg diet (95% C.I. 2520 to + infinity) NOAEC < 657 mg ai/kg diet LOAEC = 657 mg ai/kg diet Endpoint affected: mortality
850.2200	Mallard duck ( <i>Anas platyrhynchos</i> )	47146907	Acceptable	LC <sub>50</sub> > 5150 mg ai/kg diet NOAEC = 5150 mg ai/kg diet LOAEC > 5150 mg ai/kg diet Endpoint affected: none

Study	Test Species	MRID	Study Classification	Summary
850.1075	Rainbow trout ( <i>Salmo gairdneri</i> )	47135816	Supplemental (qualitative use)	<p>LC<sub>50</sub> &gt; 1000 mg/l  NOAEC = 500 mg/l  LOAEC = 1000 mg/l  Endpoints affected: mortality and sublethal effects</p> <p>There is uncertainty about the test material and test concentration in terms of active ingredient (denatonium benzoate).</p>
850.1035	<i>Crangon</i> sp.	47135817	Supplemental (qualitative use)	<p>LC<sub>50</sub> = 554 mg/l (95% C.I. 412-755)  NOAEC = 125 mg/l  LOAEC = 250 mg/l  Endpoint affected: mortality</p> <p>There is uncertainty about the test material and test concentration in terms of active ingredient (denatonium benzoate).</p>
850.1300	Water flea ( <i>Daphnia magna</i> )	47135818	Supplemental	<p><i>Parental survival</i>  NOAEC = 2 mg/l  LOAEC = 5 mg/l</p> <p><i>Reproduction (brood release and offspring per parent)</i>  NOAEC ≥ 5 mg/l  LOAEC &gt; 5 mg/l</p> <p>Nominal test concentration – assumed as denatonium benzoate</p>
850.4500	Freshwater diatom ( <i>Nitzschia palea</i> )	47135819	Supplemental (qualitative use)	<p><i>Yield (0-70.5 hr)</i>  IC<sub>50</sub> = 5.0 to 10.0 mg/L  NOAEC = 5.0 mg/L  LOAEC = 10 mg/L</p> <p><i>Growth Rate (0-45.5 hr)</i>  IC<sub>50</sub> = 6.1 mg/L (95% C.I. 5.8-6.5)  NOAEC = 5.0 mg/L  LOAEC = 10 mg/L</p> <p><i>Area Under the Growth Curve (0-70.5 hr)</i>  IC<sub>50</sub> = 5.7 mg/L (95% C.I. 5.2-6.3)  NOAEC = 5.0 mg/L  LOAEC = 10 mg/L</p> <p>Nominal test concentration – assumed as denatonium benzoate</p>